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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,894	12/15/1999	MARC PIECHACZYK	19141-007	5731

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EXAMINER	
WOITACH, JOSEPH T	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/10/2002 21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/341,894	Applicant(s) PIECHACZYK ET AL.	
	Examiner Joseph Woitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,11,13,14,20,21 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,11,13,14,20,21 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continued Prosecution Application

The request filed on November 12, 2001, paper number 19, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/341,894 is acceptable and a CPA has been established. An action on the CPA follows.

DETAILED ACTION

Please note that the Examiner of record and art unit has changed. The Examiner of record is now **Joseph T. Woitach** and the group art unit is now **1632**.

This application is a 371 National stage filing of PCT/FR98/00081, filed January 16, 1998, which claims benefit to foreign application FR 97/00540, filed January 20, 1997 in France.

Applicants' amendment filed November 12, 2001, paper number 20, has been received and entered. Claims 3, 6-8, 12, 15 and 22-30 have been canceled. Claims 1, 4, 20, 21 and 31 have been amended. Claims 1, 4, 5, 11, 13, 14, 20, 21 and 31 are pending and currently under examination.

Claim Objections

Claims 20 and 31 are objected to because of the following informalities:

In claim 20, step (1) transferring is misspelled "transfering".

In claim 31, line 2, ";" is present in the clean copy of the claims and should be deleted.

Appropriate correction is required.

Specification

For the sake of compact prosecution, the specification is objected to because of the following informalities:

In Applicants' amendment, page 6, fifth full paragraph, Applicants indicate that "[s]ignal peptides are disclosed in Figure 1a and Figure 2a of the instant specification". Upon examination of the instant specification, and the transmittal letters filed by Applicants, it appears that no drawings or figures were submitted with the instant disclosure (see for example bibliography sheet). A review of the PCT application PCT/FR98/00081, indicates that three figures were in the original PCT application. If these drawings are to be filed, the specification should contain a brief description of the figures. A review of both the instant disclosure and the PCT application did not indicate that a brief description of the drawings is present.

If drawing are submitted, appropriate correction would be required.

In addition, the specification is objected to because of the following informalities:

As indicated in the previous office actions, the instant specification contained multiple grammatical errors in English, potentially due to the direct translation of the PCT document. Upon further review and comparison of the instant disclosure and the French PCT disclosure

multiple translation errors have also been identified. For example, the passage in the instant specification on page 5; lines 7-8 recites:

- at least one therapeutic antibody gene, **or a** gene coding for a virgin unmodified and ***therefore natural antibody***, or antibody fragment...

This passage is translated from the French PCT application on page 6; lines 24-27, which recites:

- au moins un gene d'anticorps therapeutique, **c'est a dire** un gene codant pour un anticorps natif non modifie ***donc naturel***, ou **un** fragment d'anticorps...

A more literal and proper translation of the passage would recite:

-at least a therapeutic antibody gene, **which is to say** a gene coding for a unmodified native antibody ***therefore natural***, or **an** antibody fragment...

First, the translation has clearly changed the meaning of the phrase from describing types of therapeutic antibodies to seemingly listing different types of polynucleotide sequences. Secondly, a review of the immunological art in English does not provide for a term 'natural antibody'. A review of available French immunological text does not contain an equivalent term using the term 'un anticorps naturel'. In the context of the recitation it appears that the term 'naturel' may refer to the complete native antibody, which is in part supported by the recitation of possible modifications including fragments and chimeric antibodies. This portion of the specification is provided for example because Applicants have used it to amend claims to obviate art rejections. It is suggested that Applicants review the translation of the French application, in

particular, portions of the instant specification relied upon for specific terms or embodiments recited in the claims.

Appropriate correction would be required.

Sequence compliance

For the sake of compact prosecution, if the drawings from PCT/FR98/00081, filed January 16, 1998, are to be submitted as formal drawing in the instant application, it is noted that figures 1 and 2 contain polynucleotide sequences (see WO 98/31808, publication of PCT/FR98/00081). Because the sequences disclosed in the figures are encompassed by the definition for nucleotide and amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), this application fails to comply with the requirement of 37 CFR 1.821 through 1.825 for patent applications containing nucleotide and amino acid sequences.

The absence of a sequence listing for all the disclosed sequences did not preclude examination of the instant application on its merits. **However, for a complete response to this office action, Applicants must comply with 37 CFR 1.821 through 1.825 for the all the sequences disclosed in the present specification.**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

> person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 5, 11, 13, 14, 20, 21 and 31 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that signal peptides are disclosed in Figure 1a and Figure 2a of the instant specification. Though not labeled in the figure or described in figure legends, Applicants argue that these sequences are signal peptides as assessed from the information available in general on-line databases. However, Applicants note that to expedite prosecution the term signal peptide has been removed from claims 1, 20, 21 and 31. See Applicants' amendment, pages 6-7. Applicants' arguments have been fully considered but not found persuasive.

A review of claims 1 and 20 indicates that these claims still recite 'a signal peptide for the secretion of the antibody', and claims 21 and 31 still make reference to 'a sequence...permitting the secretion of said antibody'. In both cases, the claims clearly make reference to signal peptide sequences for secretion of the antibody. As noted above, the present specification does not contain figures or figure legends which reference signal peptides. Further, the mere presence of an element in a figure illustrating a cloned sequence would not support the general use of attaching this particular element or the whole genus of these elements. A close review of the instant specification indicates that the antibody produced in the example is secreted, however,

there is no clear indication or recitation in the present disclosure that this is a critical or necessary element which was specifically contemplated. The present invention is based on the observation that antibodies can be produced in genetically modified cells which do not normally produce antibodies (page 4; first lines). The description of the 'biological material' describes the antibody coding sequences, the promoters, vectors for delivery and potential target cells, however specific elements for secretion and the guidance on how they would be used are not described. Examiner would concede that if a full length cDNA, such as is illustrated in the working example, were used in the instant invention, it would inherently contain a signaling polypeptide necessary for secretion, however the instant claims encompass more than the use of full length cDNA polynucleotides encoding antibodies.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. In the instant case, specific signal peptides are not taught, nor is the use of the broad class of such

peptides specifically taught or indicated as necessary for practice of the instantly claimed invention.

Further, MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure*" (emphasis added). In the instant case, Applicants have pointed to two figures which have not been submitted. Even if the figures from the PCT were considered, neither the instant specification nor the French PCT application contain figure legends or reference to the amino terminal sequences as being signal peptides, nor is there support that these elements were critical to the instantly claimed invention. These sequences simply provide an illustration of the coding sequence for the sequences used in the working examples.

Therefore, for the reasons above and of record, the rejection is maintained.

Claims 1, 20 and 31 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

Applicants argue that Examiner has not met the initial burden for lack of enablement. Citing the MPEP and several references supporting that the disclosed methodology for

expressing proteins in non-plasmacyte cells has been demonstrated, Applicants argue that Examiner's rejection is based on the evidence in the working examples is improper. It is argued that Applicant need not provide *conclusive* evidence but merely *convincing* evidence to one of skill in the art. In light of the guidance in the instant specification and the state of the art, Applicants argue that the experimentation required to practice the claimed invention would not be undue. See Applicants' arguments, pages 7-12. Amendments to the claims and Applicants' arguments have been fully considered and found persuasive.

It is noted that the instant claims are directed to methods of making a non-plasmacyte cell which expresses an antibody and methods for using said cell for delivering an antibody to the blood system. Examiner agrees that these methods can be accomplished given the level of skill in the art and guidance in the instant specification. No therapeutic effect is recited in the claims, however, if a therapeutic affect were to be considered as part of the methods for delivery *in vivo*, the art teaches multiple epitope targets and the use of antibodies themselves for the generation of anti-idiotype antibodies. Given that the art teaches multiple antibody sequences and that the artisan could isolate other antibody sequences, and the vectors, promoters and means to transfect cells *in vitro* are routine, Examiner agrees that the experimentation needed to practice the instant invention is not undue and is enabled. Therefore, in light of the amendments to the claims, Applicants arguments, and for the reasons set forth above, the rejection is withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 11, 20, 21 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

First, please note that the previous rejections of record have been obviated by amendments to or cancellation of the claims.

Claims 1 and 20 are vague and unclear in the recitation of 'natural antibody polypeptide'. Examination of the portions of the specification pointed to for support of this amendment does not provide a specific definition of this term, however it is given as an alternative term for 'a gene coding for a virgin, unmodified' antibody (page 5, lines 5-10). Claims 1 and 20 are unclear because in each case the polynucleotide sequence for the antibody is characterized by (i) and (ii) which are modifications to gene and coding sequences of the antibody. It is unclear how 'a virgin unmodified sequence' can also be modified. It is unclear if the 'natural antibody polypeptide' is a sequences which is further modified to comprise (i) and (ii), or if a more appropriate term directed to antibodies from the same portion of the specification was intended for use in the claims. Further, the heavy chain and the light chain of an antibody or a fragment of these (*i.e.* V_H C_H V_L or C_L) are also natural antibody polypeptides. Though portions of a complete antibody molecule, they could constitute natural antibody polypeptides. There appears

to be no limitation to what a natural antibody polypeptide is, except that the sequence encoding the protein is unmodified. Additionally, the art teaches that an antibody found in nature is the result of genetic recombination which results in two proteins being produced, heavy and light chains. If the term is in reference to the gene encoding the polypeptide, does it refer to the resulting recombined sequences or each of the separate sequences in the gene. Clearly indicating the type of antibody by changing natural antibody to a more appropriate term and indicating the antibody sequences are further modified would obviate the basis of the rejection.

Claim 11 is unclear and confusing in the recitation of 'hematopoietic cells' because the instant invention as set forth in the independent claim is drawn to using non-plasmacyte cells. A plasmacyte is not specifically defined in the specification, however the art definition encompasses cells present in the plasma. Hematopoietic cells are present and can be isolated from the plasma.

Claim 21 and 31 are unclear and confusing in the recitation of 'a sequence for termination of the transcription, situated downstream from the sequence coding for an antibody molecule and permitting the secretion of said antibody molecule' because there is no nexus between signals which terminate transcription and signals for secretion of a polypeptide. Amending the claim to clearly set forth the nature and location of sequences for secretion of the protein separate from signals associated with the production of the RNA would obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 11, 13, 14, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al. (Crit. Rev. Immunol., 12(3,4):125-168, 1992).

Applicants argue that Wright *et al.* 'concerns the production of monoclonal antibodies *in vitro* by non-B cell lines' and 'does not disclose a method for the production of monoclonal antibodies *in vivo*.' See Applicants' arguments bottom of page 12.

Wright *et al.* reviews and discloses expression vectors encoding potentially therapeutic antibodies and cells comprising them which are capable of secreting recombinant antibodies into the bloodstream of mammals from genetically-modified nonlymphoid cells or of use in manufacturing genetically-modified cells comprising recombinant antibodies in vivo or ex vivo in a mammalian host (see pp. 130-131, section 6., "Nonlymphoid cell expression"). Further, Wright *et al.* discloses and reviews biological material comprising expression vectors comprising therapeutic antibody genes with elements capable of expressing and secreting into the blood circulation of mammals therapeutically effective amounts of antibody from the vector directly (see for example p. 135-136, section C., "Vectors for immunoglobulin expression" and

references therein) or from mammalian cells not naturally producing antibodies which can be genetically modified *ex vivo* by the antibody gene-containing vector implanted in a mammal (see for example p. 130-131, section 6., "Nonlymphoid cell expression"). The method used to make the products further constitutes a process manufacturing genetically-modified mammalian host (see pp. 130-131, section 6., "Nonlymphoid cell expression").

Applicants arguments that the methods of Wright *et al.* have been fully considered but not found persuasive because these arguments are directed to the intended use of a product. Please note that this reference is not relied upon as a showing of the production for any particular use. This is because the claim recitation encompassing use of the cells to secrete antibodies into the blood circulation has not been given patentable weight because the recitation occurs in the preamble. A preamble or intended use is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In the instant case, the non-lymphoid cells taught by Wright *et al.* would be capable expressing an antibody, and like hybridomas would be capable of secreting the antibody upon expression. Thus, Wright *et al.* provide the necessary guidance for methods drawn to the expression of an antibody in a non-plasmacyte cell, therefore the teachings of Wright *et al.* anticipate the claims.

Claims 1, 4, 11, 13, 20 and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Stevenson *et al.* (Ann. N.Y. Acad. Sci., 772:212-226, 1995).

Applicants argue that Stevenson *et al.* teach chimeric antibodies and vectors for deliver in vivo, not by implanted cells. See Applicants' arguments, top of page 13.

Stevenson *et al.* disclose a mammal vector encoding a therapeutic antibody containing elements capable of expressing in the blood circulation a therapeutically effective amount or for manufacturing genetically-modified cells comprising therapeutic antibodies in an mammal (see p. 215, middle of page). Stevenson *et al.* test the plasmid in both BCL1 lymphoma cells and human lymphoma cells (page 214; first full paragraph). The lymphoma cell lines are derived from hematopoietic cells and cultured *in vitro,* and thus, do not represent a plasmacyte cell. The epitope of the antibody is directed towards tumor antigens on the BCL1 tumor (page 215; middle of page). As noted above in Wright *et al.*, the use of the vectors and cells for *ex vivo* cell transplantation is not considered in the instant rejection because this encompasses an intended use which has been given no patentable weight. Stevenson *et al.* teach vectors and cells transfected with said vectors for the production of antibodies directed to tumor antigens, thus anticipated the claims.

Claims 4, 5, 11, 13, 20 and 21 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Moritz *et al.* (Proc. Natl. Acad. Sci. USA, 91:4318-4322, 1994) is withdrawn.

Applicants argue that Moritz *et al.* do not teach inserting the genetically modified cell into a mammal. See Applicants' arguments, bottom of page 13.

Moritz *et al.* disclose cells not naturally producing antibodies (e.g. cytotoxic T-lymphocytes), however these cells are present in the plasma. Because the cells are not non-plasmocyte cells, the teachings of Moritz *et al.* does not anticipate the instant claims, and therefore, the rejection is withdrawn.

Claims 1, 4, 5, 11, 14, 20, 21 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen *et al.* (Proc. Natl. Acad. Sci. USA, 91:5932-5936, 1994).

Applicants argue that Chen *et al.* teach fragments of antibodies not natural antibodies. See Applicants' arguments, page 14.

Chen *et al.* discloses cells known not to naturally produce antibodies (COS-1 and CD4+ T lymphocytes) which are genetically modified with recombinant antibody gene-containing expression vectors for *ex vivo* gene transfer of said cells for secretion of the recombinant antibodies into the blood circulation of mammals (see abstract and p. 5934). Chen *et al.* teach that the neutralizing antibodies may be useful in gene therapy protocols for the treatment of AIDS (pages 5935-3936, Discussion section). As discussed above in the 35 USC 112, second paragraph, rejection, a natural antibody can reasonably interpreted to be a fragment as long as the sequence has been obtained from a gene sequence which encodes an antibody. Therefore, in the instant case, the antibody fragments of Chen *et al.* are isolated from cells which normally express

the antibody, thus it constitutes a natural antibody. In summary, Chen *et al.* teach cell lines which have been genetically modified to express and secrete antibodies, and teach to use the methodology for the production of antiviral antibodies in the treatment of the AIDS virus, therefore anticipate the instant claims.

Claims 1, 4, 5, 11, 14, 20, 21 and 31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chen *et al.* (Hum. Gene Ther., 7:1515-1525, 8/1996).

Applicants argue that Chen *et al.* teach fragments of antibodies not natural antibodies. See Applicants' arguments, bottom of page 14.

Chen *et al.* discloses mammalian non-plasmocyte cells (i.e. COS-1 and $CD4^+$ T-lymphocytes) genetically modified by transfection with a virus vector (i.e. pAAV-Fab105) coding for a Fab antibody molecule directed against a virus (i.e. HIV) for secretion of the recombinant antibodies into the blood circulation of mammals (see e.g. abstract). The vector in the transduced cells comprises Fab-encoding nucleotide sequences operatively linked to a promoter and nucleotide sequence elements encoding a signal peptide. The Fab-encoding vector comprises two distinct nucleic acids, one coding for one fragment of the heavy chain variable region and the other coding for another region of the light chain variable region. As noted immediately above and as disucussed above in the 35 USC 112, second paragraph, rejection, a natural antibody can reasonably be interpreted to be a fragment as long as the sequence has been obtained from a gene sequence which encodes an antibody. Therefore, in the instant case, the

antibody fragments of Chen *et al.* are isolated from cells which normally express the antibody, thus it constitutes a natural antibody. Therefore, the cell lines which have been genetically modified to express and secrete antibodies, and the methodology for the production of antiviral antibodies in the treatement of the AIDS virus in a patient taught by Chen *et al.* anticipate the instant claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Patsy Zimmerman whose telephone number is (703)308-8338.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

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